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Évaluation de la qualité des essais contrôlés randomisés publiés en anesthésie ambulatoire par l'intermédiaire d'une checklist formalisée

Chérifa Cheurfa

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(Diplôme d'état)

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**Évaluation de la qualité des essais contrôlés randomisés
publiés en anesthésie ambulatoire par l'intermédiaire d'une
checklist formalisée**

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ABBREVIATIONS

RCTs : *Randomized Controlled Trials*

CONSORT : *Consolidated Standards of Reporting Trials*

CONSORT-NPT : *Consolidated Standards of Reporting Trials for Non-Pharmacological Treatment*

TIDieR : *Template for intervention Description and Replication*

ASA : *American Society of Anesthesiologists*

INTRODUCTION

1-De l'essai contrôlé randomisé au rapport d'informations dans les publications

1-1- Les essais contrôlés randomisés

1-1-1- Définition

Un essai clinique contrôlé randomisé est une étude scientifique expérimentale dans laquelle une intervention en santé est comparée à une autre intervention ou à l'absence d'intervention. Cette intervention peut être une méthode diagnostique, une méthode pronostique, un dispositif de surveillance ou une technique de soins. Lorsque cette intervention concerne des traitements, on parle alors d'essai thérapeutique¹.

Ce type d'étude a la particularité d'avoir une démarche méthodologique très rigoureuse. En effet, l'attribution de l'intervention aux sujets est contrôlée. L'assignation des sujets se fait au hasard, par tirage au sort, dans un groupe qui reçoit l'intervention testée ou dans un groupe recevant une autre intervention ou l'absence d'intervention. Ni les investigateurs de l'étude, ni les sujets ne choisissent le groupe dans lequel ils vont être assignés. On ajoute souvent à ce critère méthodologique la notion d'aveugle. L'intervention réalisée sur le sujet se fait alors à l'insu de celui-ci et/ou des investigateurs qui prodiguent l'intervention ou qui évaluent les résultats. On parle de simple ou double aveugle²³.

Enfin, pour évaluer l'effet de cette intervention, un ou des critères de jugements sont choisis par les investigateurs. L'organisation de l'essai doit minimiser les facteurs pouvant influencer de façon non contrôlée l'essai et l'interprétation de ces critères de jugement. On parle de limiter les risques de biais dans l'essai⁴.

Ainsi, du fait de sa force méthodologique permettant d'avoir des groupes comparables en tout point à l'exception de l'effet du traitement, un essai clinique contrôlé randomisé permet d'établir un lien statistiquement fiable de cause à effet et donc de conclure ou non à une différence d'efficacité causée par le traitement³. On peut les opposer aux études observationnelles, qui ne peuvent pas conclure à des relations de cause à effets mais

seulement à des constatations d'effet ou de lien, dont la cause peut être associée ou due à d'autres facteurs.

1-1-2- Niveau de preuve

Avec son article publié sur le traitement de la tuberculose pulmonaire par Streptomycine en 1948, Austin Bradford Hill marque l'avènement du premier essai contrôlé randomisé publié en médecine et d'une nouvelle ère : celle de la médecine fondée sur les preuves⁵ (*Evidence Based Medicine*). Le nombre d'essais contrôlés randomisés réalisés et publiés n'a fait qu'augmenter depuis lors. Ils sont reconnus comme la référence et le gold standard en tant que schéma d'étude à réaliser afin d'évaluer l'effet des interventions en santé et plus particulièrement, l'efficacité et les effets secondaires des traitements⁶.

Les pratiques en médecine sont guidées par des recommandations de bonnes pratiques. Leurs élaborations sont fondées sur une revue et une synthèse méthodique des études de la littérature à un instant donné. Un système de niveaux de preuves des études scientifiques a ainsi été établi. Parmi le niveau de preuve des études, l'essai contrôlé randomisé a le niveau le plus élevé (fort) afin de répondre à une question donnée sans risque de biais majeur⁷⁸.

Il convient tout de même de préciser que les essais contrôlés randomisés ne sont pas les plus simples à réaliser, cela demande une organisation complexe avec des compétences particulières, une méthodologie rigoureuse, des ressources coûteuses et un temps d'organisation long. Par ailleurs, il y a des domaines où les essais contrôlés randomisés sont moins adaptés, comme l'étude des maladies rares ou des domaines où l'éthique ne permet pas la répartition aléatoire d'un traitement à un sujet malade³.

1-2- La qualité du rapport d'informations dans les publications

1-2-1- Les publications scientifiques

La publication d'articles scientifiques en médecine est un outil incontournable et indispensable de la communication scientifique. Elle permet aux chercheurs de transmettre les résultats de leur recherche à la communauté scientifique et ainsi de participer aux avancées et d'améliorer les pratiques dans le domaine de la santé. L'article scientifique est rédigé par les auteurs de l'étude sous un format recommandé et soumis à un journal. Il sera alors relu par les pairs que l'on nomme des « *peer reviewer* », dont le rôle est de s'assurer de la validité de la méthodologie utilisée, de la cohérence des résultats communiqués et de la conclusion⁹¹⁰.

1-2-2- Importance de la qualité du rapport des informations

Sans une description complète des interventions publiées dans les articles scientifiques, les cliniciens ne peuvent pas mettre en œuvre de façon fiable des interventions qui se révèlent utiles et les autres chercheurs ne peuvent pas reproduire ou exploiter les résultats des recherches. La description de l'intervention ne se limite pas à fournir une étiquette ou la liste des ingrédients. Les principales caractéristiques - y compris la durée, la dose ou l'intensité, le mode d'administration, les processus essentiels et la surveillance - peuvent toutes influencer sur l'efficacité et la reproductibilité, mais sont souvent absentes ou mal décrites. Pour les interventions un peu complexes, ce détail est nécessaire pour chaque composante de l'intervention¹¹.

1-2-3- Recommandations pour le rapport des informations

L'énoncé des normes consolidées de présentation des rapports des essais cliniques (CONSORT)¹² de 2010 suggère actuellement au point 5 que les auteurs devraient faire rapport

sur " les interventions pour chaque groupe avec suffisamment de détails pour permettre la reproduction, y compris comment et quand elles ont été effectivement administrées ". Il s'agit là d'un conseil approprié, mais d'autres orientations semblent nécessaires : malgré l'approbation de l'énoncé CONSORT par de nombreuses revues, les rapports sur les interventions sont insuffisants. Un petit nombre d'énoncés d'extension de CONSORT contiennent des directives élargies sur la description des interventions, comme les interventions non pharmacologiques¹³ et des catégories spécifiques d'interventions, comme l'acupuncture et les interventions à base de plantes médicinales^{14,15}, TIDieR (*Template for Intervention Description and Replication*)¹⁶. L'objectif est d'améliorer l'exhaustivité des rapports et, en définitive, la possibilité de reproduire les interventions.

1-2-4- État des lieux de la littérature sur l'évaluation de la qualité des rapports d'études

Plusieurs essais ont déjà évalué la qualité des rapports des essais contrôlés randomisés dans différents domaines et ont montré une qualité médiocre des rapports tels que la chirurgie^{17,18}, l'oncologie¹⁹ ou l'oto rhino laryngologie²⁰. Par exemple, une analyse a révélé que seulement 11 % des 262 essais cliniques de chimiothérapie anticancéreuse fournissaient des détails complets sur les traitements à l'étude²¹. Les éléments les plus souvent manquants étaient l'ajustement posologique et les " prémédications " avec même 16 % des essais cliniques qui omettaient la voie d'administration du médicament.

En anesthésie, des études existent également dans des contextes spécifiques. Fergusson et coll. ont constaté l'absence de rapports dans les essais précliniques²² et Janackovic et coll. dans les résumés des essais contrôlés randomisés²³. Shanthanna et coll. ont analysé la qualité des rapports des essais pilotes ou des essais de faisabilité à l'aide de la liste de contrôle CONSORT et ont conclu que le rapport était de mauvaise qualité²⁴. Néanmoins, Herdan et coll. ont démontré une amélioration de la qualité des rapports avant et

après la publication de CONSORT dans la prévention de l'hypotension après une anesthésie spinale pour la césarienne²⁵. Par contre, aucune évaluation de ce type n'a été effectuée dans le domaine spécifique de l'anesthésie ambulatoire, alors même que c'est un enjeu considérable en termes de santé publique mondiale.

2-L'anesthésie ambulatoire : définition et enjeux

L'anesthésie ambulatoire consiste à administrer un anesthésique à un patient qui subit une intervention chirurgicale et qui va quitter l'hôpital le jour même. Il n'y a pas d'hospitalisation la nuit suivant la chirurgie. Ce type de soins s'est développé au cours des dernières années²⁶²⁷. Il offre les avantages d'une meilleure qualité de vie pour les patients avec un retour précoce à domicile, un risque moindre d'infections nosocomiales, des coûts d'hospitalisation réduits et un taux d'interventions possibles plus élevé²⁸²⁹³⁰. La réduction des coûts liés à la baisse du nombre d'hospitalisation et à l'augmentation du nombre d'interventions réalisable est devenu un réel enjeu pour les tutelles³¹³². Ce système de soins nécessite une organisation spécifique, avec un circuit patient complet adapté au patient externe, des locaux compatibles et un personnel dédié et formé. Cela nécessite également l'élaboration de plusieurs protocoles d'anesthésie assurant la qualité et la sécurité des patients ne séjournant pas à l'hôpital, notamment en termes de réduction des risques de complications périopératoires : nausées/vomissements, complications cardiovasculaires, douleur, troubles du comportement, fatigue et immobilisation³³³⁴. Le choix des molécules et des techniques d'anesthésie a un impact direct sur ces événements, sur le congé du patient et sur l'échec potentiel de l'ambulatoire. Par exemple, l'utilisation de l'anesthésie locorégionale à la place ou en combinaison avec l'anesthésie générale améliore l'efficacité de l'analgésie ainsi que la qualité de vie des patients³⁵³⁶. De même, la disponibilité d'anesthésiques à action ultra-courte réduit les complications liées à la consommation et à l'accumulation de produits anesthésiques et donc les effets secondaires tels que nausées, vomissements, hypotension artérielle et dépression respiratoire³⁷. La prise en charge anesthésique ambulatoire des patients reste complexe, en raison d'une dimension non pharmacologique, de la multiplicité des acteurs et

de la nécessité d'un parcours patient spécifique. L'anesthésie ambulatoire est donc un exemple d'intervention complexe. Toutes ses composantes - anesthésie, interventions chirurgicales et organisation du système ambulatoire - doivent être correctement rapportées dans les essais afin d'assurer la reproductibilité³⁸.

3-Rationnel du travail de thèse

3-1-Objectif

Du fait de l'importance de la qualité du rapport des interventions dans les articles scientifiques d'une part, et du fait de la multi dimension et la complexité de l'intervention en anesthésie ambulatoire, nous avons donc décidé d'évaluer la qualité de la description de l'intervention dans les essais contrôlés randomisés dans le domaine de l'anesthésie ambulatoire.

3-2-Mapping des essais

Dans un premier temps, nous avons réalisé une cartographie des essais contrôlés randomisés en anesthésie ambulatoire, en évaluant différents éléments qui permettent de situer l'état des publications dans ce domaine : date et journaux de publications, évolution dans le temps des publications, type d'outcomes et d'interventions, population ciblée dans les études. Ces éléments peuvent avoir un intérêt pour l'interprétation des résultats et la reproductibilité des interventions en pratique. Une population sans comorbidités n'a pas les mêmes risques de faire des complications post opératoires et l'issue de l'intervention peut en être impactée, et de ce fait la sortie le jour même remise en cause. Il est donc important de savoir quelle typologie de patients est incluse dans ces études.

3-3-Evaluation de la qualité du rapport des interventions et conception d'une checklist

Dans un second temps, nous nous sommes intéressés à l'évaluation de la qualité du rapport des interventions dans ces études. Nous sommes basées sur les recommandations

existantes concernant la manière de rapporter des interventions dans les essais. Du fait la complexité et de la multi dimensions de l'intervention en anesthésie ambulatoire, nous avons finalement élaborer une checklist adaptée spécifiquement au domaine de l'anesthésie ambulatoire prenant en compte trois dimensions : la procédure chirurgicale, la procédure anesthésique en elle-même et l'organisation du système d'ambulatoire.

Les paragraphes regroupant le matériel et les méthodes, les résultats et la discussion ont été rédigés sous forme d'un article en anglais.

Assessment of reporting of intervention in RCTs evaluating ambulatory anesthetic procedure: a cross sectional study

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Abstract (253/250)

Introduction: Ambulatory anesthesia has been emerging in recent years, guided by scientifically based guidelines. Our objective was to assess the quality of the reporting of intervention in randomized controlled trials (RCTs) in the field of ambulatory anesthesia.

Methods: We selected RCTs assessing anesthetic procedure in ambulatory surgery, indexed in Medline from 2008 to 2018 and published in the first 20 journals in Anesthesia and General medicine. After mapping the publications, interventions and outcomes, we evaluated the quality of the reporting of intervention using a new adapted checklist based on the CONSORT, CONSORT-NPT and TIDieR recommendations, considering three essential dimensions of ambulatory anesthesia.

Results: We included 52 trials. Overall, the quality of the intervention reporting using the 3 dimensions was correct in 41% of the studies (mean: 21.3, sd: 17.8). Concerning the anesthesia procedure, 45 studies (87%) correctly reported the elements of our checklist. The reproducibility of anesthetic interventions was evaluated as very good by two independent anesthesiologists: 43 interventions (83%) out of 52 with a mean score of 7.2/10. While the surgical procedure was correctly reported in 25 studies (48%) and the organization of the ambulatory system in 23 studies (44%).

Conclusion: The anesthesia procedure is correctly reported in the RCTs, but due to its complexity, the evaluation of the anesthesia procedure requires several dimensions to be considered. The ambulatory care system and the surgical procedure remain poorly reported which may impede reproducibility and needs to be improved. The use of our new checklist based on the guidelines can be an exhaustive approach to this assessment.

Keywords: ambulatory anesthesia, RCTs, complex intervention, reporting

Introduction

Ambulatory anesthesia consists in providing an anesthetic procedure to a patient receiving a surgical procedure and leaving the hospital on the same day. There is no planned night hospitalization for this type of patient. This type of care has been expanding in recent years^{1 2}. It offers the advantages of improved quality of life for patients with early return home, lower risk of nosocomial infections, reduced hospitalization costs and higher turnover with more possible interventions^{3 4 5}. Such care system requires a specific organization, with an entire patient circuit adapted to the outpatient, compatible premises, dedicated and trained staff. This has also required the development of several anesthesia protocols providing quality and safety for patients who do not stay in hospital, particularly in terms of reducing the risks of perioperative complications: nausea/vomiting, cardiovascular complications, pain, behavioral disorders, fatigue and immobilization^{6 7}. Outpatient anesthetic management of patients remains complex, due to this non-pharmacological dimension, the multiple stakeholders and the need for a specific patient path. All its components — anesthesia, surgical procedures and organization of the ambulatory system — need to be correctly reported in the trials in order to ensure reproducibility⁸.

In their clinical practice, physicians use high-quality studies with a high level of scientific evidence. This is even true for the elaboration of recommendations by expert groups and academic societies. Randomized controlled trials (RCTs) are considered to be the best type of study for addressing questions about the effectiveness of therapy (or of interventions). Guidelines on how to conduct and to report interventional pharmacological trials have been developed. The Consolidated Standards of Reporting Trials (CONSORT) — first version created in 1996 and revised in 2010 — is a checklist of items designed to improve the quality of the trial reporting in publications^{9 10}. Then, guidelines have been extended for non-pharmacological trial interventions, the CONSORT-NPT (Consolidated Standards of Reporting Trials for Non-Pharmacological Treatment) and TIDieR (Template for intervention Description

and Replication) which are now recognized by most peer-reviewed journals^{11 12}. As a complex intervention, anesthesia ambulatory procedures trials should follow these guidelines. However, adherence to these recommendations improves the quality of randomized controlled trials' reporting^{13 14}, they are far from being fully applied¹⁵⁻¹⁷.

Therefore, we conducted a systematic review to identify randomized controlled trials (RCTs) assessing ambulatory procedures in order to evaluate the quality of reporting of anesthesia ambulatory procedure: 1) performing a mapping of the publications, the type of institution, the type of surgical procedures and the outcomes; and 2) creating a checklist to evaluate the quality of the intervention's reporting, adapted to the field of ambulatory anesthesia, based on these validated guidelines.

Methods

1- Search strategy

We search in Medline RCTs published in the 10 anesthesia journals with higher impact factor and in the 10 general medicine journals with higher impact factor, according to Journal Citation Report 2018, from 2008 to 2018. In these high-impact factor journals, the quality of the reporting of information in studies is better. There was no restriction on language, country or publication status. We used the recommended Mesh terms standardized vocabulary for Medline database. The search strategy is detailed in Appendix 1. We used: - the Cochrane highly sensitive search strategy for identifying randomized trials in Medline, - the different vocabulary for anesthesia and ambulatory care, -20 journal names, -limits set for the specific time period of interest (years of publication 2008-2018). The terms used and their definition, according to the International Association for Ambulatory Surgery, were detailed in Appendix 2. We conducted the search on June 2019.

2- Inclusion criteria

We included any RCTs comparing any anesthetic procedure — e.g., general anesthesia, regional anesthesia, intravenous anesthesia, spinal anesthesia, caudal anesthesia — whatever the place of the trial location, whatever the population studied, whatever the timing of the surgery (urgent or scheduled) and pre, per or postoperative studies. We excluded trials on local anesthesia, topical anesthesia, and verbal or hypnosis anesthesia when it was the single anesthetic act.

3- Selection of trials

Two reviewers (C.C and B.P) examined independently titles, abstracts, and full-texts to assess the eligibility of each report. Disagreements were discussed with a third reviewer for find a consensus (P.C). We listed the reasons of non-eligibility of full-text trials. All the selection process has been performed with Covidence software¹⁸.

4- Data extraction

The data were extracted from reports by the two reviewers (C.C and B.P) who used a standardized data extraction form. From each study, we extracted the following characteristics:

General characteristics:

- The Journal and its impact factor (Clarivate Analytics)
- Date of publication
- Location of the trial
- Type of center: academic center, public hospital center, private center of public utility, or lucrative private center
- Monocentric or multicentric study

General characteristics of included RCTs:

- Study identification
- The number of patients included
- Population characteristics: age, sex, ASA score, comorbidities (e.g., cardiopathy, lung cancer...)
- The type of outpatient surgery concerned (e.g.: inguinal hernia in digestive surgery, hallux valgus in orthopedic surgery, cataract in ophthalmic surgery).

We classified them into surgical categories presented in Appendix 3.

Reporting of interventions:

To describe the ambulatory anesthetic procedure, we have developed a specific checklist to assess the quality of the procedure report. We used CONSORT reference items, with the CONSORT-NPT extension and the TIDieR checklist. Two anesthesiologists and two methodologists participated in the development of this checklist. The CONSORT, CONSORT-NPT and TIDieR checklist are provided in Appendix 4, 5 and 6. **The specific used checklist is provided in Table 1. This checklist assessed three aspects of the ambulatory anesthetic procedure: data on the surgery, data on the anesthetic procedure and data on the organization of the ambulatory care.**

Table 1. Checklist to assess the reporting of interventions

Field	Items description	Answers	
1-Surgery	1-Are there any details about the surgery?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	2-Number of providers?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	3-Professional category of providers? ▪ Doctor	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	▪ Resident	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	▪ Nurse	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	▪ Others	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	4-Description of expertise of each provider? (formation or background or training)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	5-Description of surgery procedure used?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
6-If yes: Name of the surgical technique	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Delivery method	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Sequences of different steps	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
7-Validation of preoperative checklist?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
8-Details on perioperative care?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
2-Anesthesiology	9-Number of providers?	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	10-Professional category of providers? ▪ Doctor	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	▪ Resident	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	▪ Nurse	<input type="checkbox"/> Yes	<input type="checkbox"/> No
	11-Description of expertise of each provider? (formation or background or training)	<input type="checkbox"/> Yes	<input type="checkbox"/> No
12-Description of each procedure used in the intervention?	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
If yes: Name of the anesthesia technique	<input type="checkbox"/> Yes	<input type="checkbox"/> No	
Delivery method	<input type="checkbox"/> Yes	<input type="checkbox"/> No	

	<p>Dosage and adjustment</p> <p>Dosage timing</p> <p>Sequences of different steps</p> <p>Monitoring method</p> <p>13-Validation of preoperative checklist?</p> <p>14-Details on post ambulatory follow up?</p> <p>If yes, how? Who</p> <p style="padding-left: 40px;">When</p> <p style="padding-left: 40px;">How</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
3-Organizational stream	<p>15-Precision of the existence of organized care system?</p> <p>If yes, Specialized structure/local?</p> <p style="padding-left: 40px;">Specialized consultation perioperative?</p> <p style="padding-left: 40px;">Dedicated staff?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
4-Standardization	<p>16-Is there a standardization process of the intervention?</p> <p>If yes, How?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
5-Modification/ Tailoring	<p>17-If the intervention was planned to be personalized?</p> <p>If yes, How?</p> <p>18-Are the changes of intervention procedure during the study mentioned?</p> <p>If yes, How?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
6-Activity/ Capacity of the center	<p>19-Is mentioned the volume of the center?</p> <p>If yes, How much?</p>	<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
7-Reproductibility	<p>20-Is the intervention reproducible? * Note : /10</p> <p><i>*Subjective evaluation by an anesthesiologist</i></p> <p style="text-align: center;"> </p>	<input type="checkbox"/> Yes <input type="checkbox"/> No

Outcomes:

- Primary outcome: the quality of the intervention reporting using the 3 dimensions
- Secondary outcomes included:
 - the quality of the intervention reporting for each dimension
 - Category of outcomes. The categories are listed in Appendix 7

5- Statistical analysis

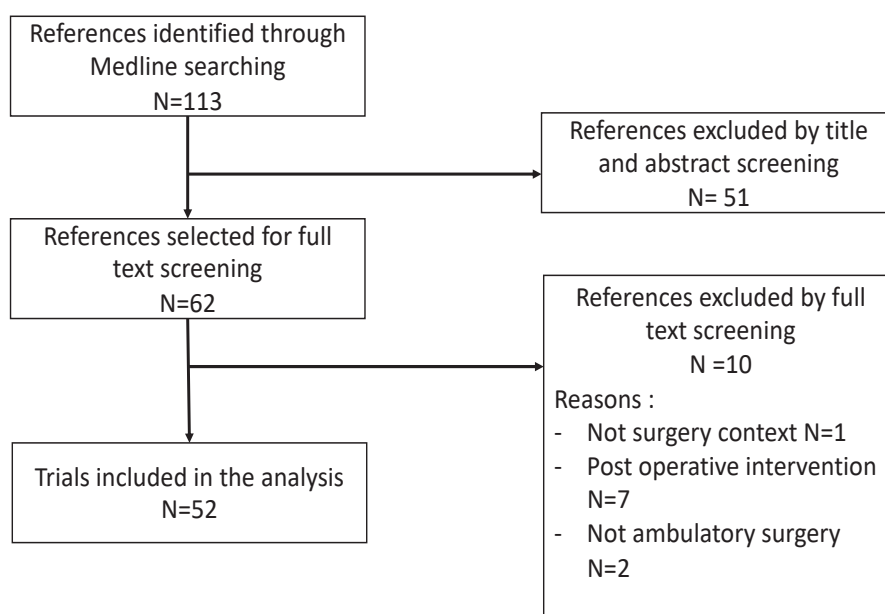
Data for qualitative variables were expressed with frequencies and percentages. Data for quantitative variables were expressed with mean and standard deviation or median and inter quartile ranges (IQR). Database management were done on Excel and all analyses were conducted using R software, version 3.4.2¹⁹.

Results

1- Search of literature and selection of trials

The flow chart of trials selection is presented in Figure 1. The electronic search yielded 113 references, of which 51 were excluded after titles and abstracts screening. Ten trials were excluded on full-text: 7 reporting postoperative procedures, 2 not reporting outpatient surgery, and 1 not reporting surgery. Finally, 52 trials were included in the analysis. Eighty-three of the trials were published in 6 anesthesia journals with impact factors greater than 3 (from 3.4 to 6.4 for the best anesthesia journal, *Anesthesiology*).

Fig1. Flow chart of trials selection



Legends: The search was conducted on June 2019

2- Characteristics of the RTCs

The general characteristics of RCTs are summarized in Table 2 and their individual characteristics are detailed in Appendix 8.

The number of published RCTs has decreased in recent years, from 21 trials (42%) in 2008-2010 to 11 trials (21%) in 2015-2018. The countries that initiated these trials are mainly North America with 25 trials (48%) and Europe with 19 trials (36%). Forty-nine trials (94%) were mono-centric and mainly carried out in University hospitals (41 trials (79%)).

Regarding population, the majority of trials (37 trials (71%)) included less than 100 patients. Trials included more than 400 patients represented only 2% of the trials. The mean number of randomized patients was 44 (sd:29.8). The majority of patients were men whose medical condition was generally preserved: 38 trials (73%) excluded patients with an ASA score of IV,

24 trials (46%) excluded patients with an ASA III score. The majority of patients were so ASA I or II patients without co-morbidities. However, the detailed comorbidities were not reported in the trials. Orthopedic surgery interventions accounted for 29 trials (56%), visceral surgery for 8 trials (15%) and gynecological surgery for 6 trials (11%). Concerning the intervention in anesthesia, 49 trials (90%) were pharmacological, 37 trials (70%) concerned loco regional anesthesia, 9 trials (17%) general anesthesia, 4 trials (8%) anxiety and 2 trials (4%) perioperative nausea and vomiting.

Table 2. General characteristics of trials

Characteristics	Number of trials, n (%)
Year of publication	
2008-2010	21(42)
2011-2014	20(39)
2015-2018	11(21)
Journal	
Anesthesia and Analgesia	11(21)
British Journal of Anaesthesia	10(19)
Canadian Journal of Anesthesia	7(13)
European Journal of Anaesthesiology	6(12)
Regional Anesthesia and Pain Medicine	5(10)
Anesthesiology	4(8)
Others	9(17)
Type of center	
Academic Hospital	41(79)
Non academic Center	11(21)
Mono-center	49(94)

Multi-center	3(6)
Location of study	
North America	25(48)
Europe	19(36)
Australia	3(6)
Asia	3(6)
Africa	2(4)
Population	
· Number of patients included	
0-100	37(71)
101-200	10(19)
201-300	4(8)
>400	1(2)
· Sex	
Trials with majority of men	29(56)
Trials with majority of women	12(23)
NA	11(21)
· ASA score excluded	
I	0(0)
II	1(2)
III	24(46)
IV	38(73)
NA	14(27)
Surgery type	
Orthopedy	29(56)
Viscerology	8(15)
Gynecology	6(11)
Plastic	3(6)
Urology	2(4)

Others	4(8)
Type of intervention	
Pharmacological	47(90)
Non-pharmacological	5(10)
Type of anesthesia	
Locoregional Anesthesia	37(71)
General Anesthesia	9(17)
Anxiety	4(8)
Nausea-Vomiting	2(4)
Outcome type	
Efficacy	49(94)
Safety	2(4)
Efficacy and Safety	1(2)

The detail of the outcomes and their evaluation time are shown in Table 3. The outcome was efficacy for 49 trials (94%), safety for 2 trials (4%) and both efficacy and safety for 1 trial (2%). Pain represented the main outcome (22 trials (41%)), followed by the effect of loco regional anesthesia (10 trials (19%)) — e.g., installation time of the sensitive or motor block, duration and removal of the sensitive or motor block—, the hospital discharge for 5 trials (10%), the occurrence of adverse events for 5 trials (10%) and sleep after general anesthesia for 4 trials (8%). Only 2 trials (4%) evaluated quality of life. Outcomes were assessed within 24 to 72 hours after surgery in 16 trials (31%). Eleven trials (21%) assessed the outcome before discharge from the ambulatory department on the same day. Eight trials (15%) assessed the outcome within 8 postoperative days and 8 trials (15%) in postoperative immediately before discharge from the recovery room. Only 6 trials (12%) evaluated the outcome on per operative. On average, the median delay for assessment was 24 hours [IQR: 24-168].

Table 3. Characteristics and evaluation of outcomes

Characteristics	Number of trials, n (%)
Type of outcome	
Pain	22(41)
Loco regional anesthesia	10(19)
Hospital discharge	5(10)
Adverse events	5(10)
Level of hypnose after general anesthesia	4(8)
Quality of Life	2(4)
Oropharyngeal leak pressure	3(6)
Cumulative drug dose	1(2)
Timing of evaluation	
Postoperative before discharge of hospital	16(31)
Postoperative within 24 to 72 hours	11(21)
Postoperative at day 8	8(15)
Postoperative before discharge of recovery room	8(15)
Peroperative	6(12)
Preoperative	1(2)
Not Available	2(4)

3- Reporting of interventions:

Overall, the quality of the intervention reporting using the 3 dimensions was correct in 41% of the studies (the checklist mean is 21.3, sd:17.8 for all the studies).

Concerning the surgical dimension, the results are presented in Figure 2A and Appendix 9. **Twenty-five trials (48%) reported elements concerning the surgical procedure**, 11 trials (21%) the specific name of the technique used, 3 trials (6%) the technique used and none the different steps of the surgery. Only 6 trials (12%) reported the number of surgical procedures, no trials reported the professional category of providers and 1 trial (2%) reported the level of expertise of the providers. Concerning the surgical act, no report concerning the validation of a preoperative safety checklist was found. Concerning perioperative surgical care, 5 trials (10%) reported information.

Concerning the anesthesia dimension, the results are presented in Figure 2B and Appendix 9. **Forty-five trials (87%) reported anesthetic procedure.** Fifteen trials (29%) reported the number of providers and 26 trials (50%) reported the professional category of providers. Their detailed experience was reported only in 9 trials (17%). For the anesthesia technique used, more than two thirds of the trials reported a description of the procedure: 52 trials (100%) reported the name of the technique, the delivery method, the dosage used, and the adjustment made during or after the procedure depending on clinical parameters. Thirty-two trials (62%) reported the timing of the different administrations, 44 trials (85%) correctly reported the sequence of the different steps during the procedure, and 35 trials (67%) reported the monitoring method used to monitor anesthesia. Twelve trials (23%) reported the validation of a preoperative checklist. Forty-one trials (79%) provided details on follow-up after ambulatory care, 23 trials (44%) specified who was doing the follow-up, 42 trials (81%) specified when the follow-up was done and 41 trials (79%) specified how the follow-up was done. We also evaluated, using items 16 and 17, whether the ambulatory anesthesia procedure was standardized and whether the changes to the procedure were planned in advance in the protocol and whether the changes actually made were well reported afterwards. Twenty-two trials (42%) reported planned protocol changes based on patient clinical parameter variations and 19 trials (37%) reported how they proceed. Ten trials (19%) reported changes in the intervention during the trial and 8 trials (15%) reported how this change was made. Concerning

standardization, reproducibility and organization, results are presented in Figure 2C and Appendix 9. Forty-seven trials (90%) reported a method of standardizing the intervention. Finally, the reproducibility of anesthetic interventions was evaluated as very good by two independent anesthesiologists: 43 interventions (83%) out of 52 with a mean score of 7.2/10 (item 20).

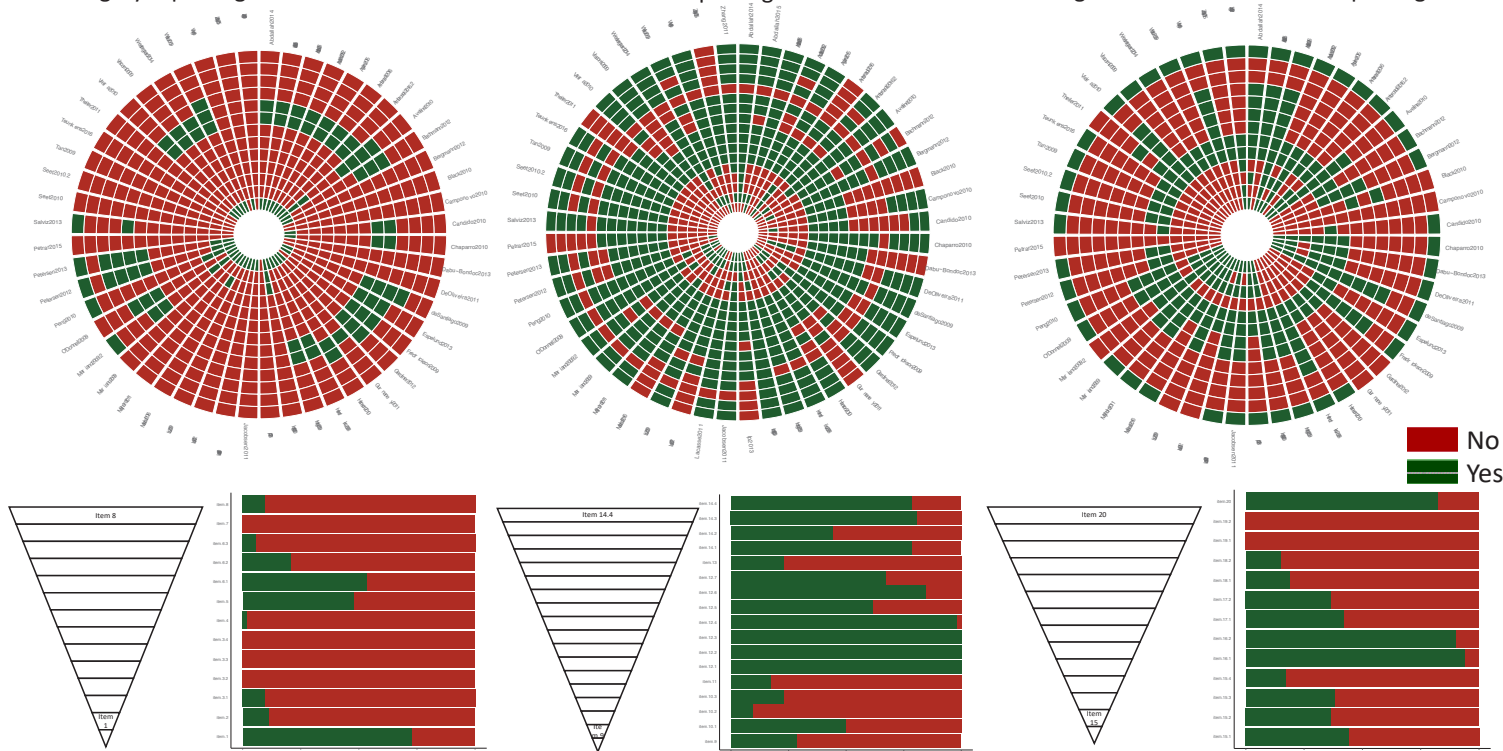
Concerning the organization of the ambulatory care stream, **the information was reported in 23 trials (44%)**: 19 trials (37%) reported a specifically ambulatory structure or stream, 20 trials (38%) reported a dedicated pre or postoperative consultation and 9 trials (17%) reported a dedicated staff for this ambulatory management. No trials have reported the volume of ambulatory surgical activity at the centers (item 19).

Fig2. Results of intervention reporting

2A. Surgery reporting

2B. Anesthesia reporting

2C. Organizational care stream reporting



Legends: This figure presents the reporting of each item of the checklist used in our study (Table 1). The green color means that the item was reported in the trial and the red color not.

2A is dedicated to surgery, 2B to anesthesia and 2C to organizational care stream.

Each spoke represents one of the 52 included trials. Every concentric circle represents one of the item in the checklist (for instance item 1 to 8 for 2A, 9 to 14 for 2B and 15 to 20 for 2C).

Bar plots at the bottom is a representation of the reporting, per item of the checklist, across the 52 included RCTs.

Discussion

We have initiated an evaluation of the quality of reporting of intervention in randomized controlled trials reporting an anesthesia procedure in ambulatory surgery. This assessment is essential because it is on these elements that clinicians and experts base their practice and guidelines. The current guidelines on the intervention reporting are not sufficient and are not perfectly adapted to this field of ambulatory anesthesia. Moreover, our study shows the complex dimension of ambulatory anesthesia intervention and highlights the difference in the reporting of each component and revealed the need to improve the reporting of surgical procedures and the organizational dimension of the ambulatory care system. This last dimension is an essential dimension that is too often forgotten and can have an impact on the center's activity (existence of a dedicated system, dedicated staff, well-organized post-operative follow-up).

Indeed, several elements will have a direct impact on the postoperative outcome of the anesthesia procedure, and therefore on the patient's discharge on the same day. As such, our checklist, based on the guidelines and considering the surgical and organizational dimensions, allows us to best reflect the anesthesia procedure in ambulatory surgery and the gaps associated with it. There is no equivalent study in anesthesia using an adapted and dedicated checklist. An equivalent methodology was used in infectiology for RCTs evaluating antiretroviral therapy by adding elements related to protocol deviations and ethical aspects to the CONSORT. They showed that more than 70% of RCTs were correctly reported²².

The importance of an high-quality reporting in published RCTS has been consistently highlighted in the literature in recent years^{23 24}. This ensures that the interventions investigated in the trials are as reproducible as possible, so that readers have all the information they need for clear, transparent and scientific interpretation²⁵. Several trials have already assessed the quality reporting in RCTs in different fields and showed poor quality of reporting in trials such as surgery^{26 27}, oncology²⁸ or otolaryngology²⁹. In anesthesia, studies also exist in specific contexts. Fergusson *et al.* found a lack of reporting in preclinical trials³⁰, and Janackovic *et al.* in the abstracts of RCTs³¹. Shanthanna *et al.* analyzed the quality of reporting in pilot or feasibility trials using the CONSORT checklist and concluded that the report was of poor quality³².

Nevertheless, Herdan *et al.* demonstrated an improvement in the quality of reporting before and after the publication of the CONSORT in the prevention of hypotension after spinal anesthesia for cesarean³³.

The mapping section highlights the population of interest, mainly healthy patients without major co-morbidities. These results do not apply to a less-healthy population, which can have an impact on surgical and anesthesia tolerance and therefore hospital discharge. It has also been shown that trials evaluate the effectiveness of interventions more than their safety. Safety, which is nevertheless an essential element of management because it is on the basis of these safety criteria that the patient can leave the hospital in safety on the same day: postoperative nausea, vomiting, hypotension or discomfort. In addition, our study showed a decrease in RCT publications even though ambulatory surgery rates have increased in recent years. This could be explained by the fact that RCTs are not easy to carry out, remain expensive and time-consuming, require methodological skills and may be difficult for specific conditions or ethical reasons. Observational studies are easier for physicians to conduct in some cases and one might think that their publication has recently increased^{20 21}.

Our study has several limitations. First, we focused our search on the 10 higher impact factor journals in General Medicine and 10 higher impact factors in Anesthesia with a median Impact Factor at 3.455[3.4-6.5]. We so focused on the best part of publications without knowing what happens for other publications. But we can think that the quality of reporting for these trials would be worse. Second, we restricted the search to 2008 to 2018 to provide a current representation of the quality of reporting and to capture the recommendations' impact (such as CONSORT). Moreover, following such guidelines is mandatory for several years by the journal's editors³⁴⁻³⁶. Third, as previously mentioned, we choose to focus on RCTs rather than observational studies, because they remain the gold standard, and the place of observational studies in evidence-based medicine remains questionable³⁷⁻³⁹.

Conclusion

High-quality reporting of RCTs is essential for reproducibility and transparency. Using a dedicated checklist to ambulatory anesthesia, our study found a high-quality reporting for the anesthetic procedure but highlights the need to improve the reporting of surgical procedure and organization of the ambulatory care system.

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Authors' contributions

CC was involved in the study conception, selection of trials, data extraction, data analysis, interpretation of results, and drafting of the manuscript. BP was involved in the selection of trials and data extraction. PC was involved in the study conception, the data analysis, interpretation of results, and drafting of the manuscript. IB and VC was involved in the study conception, interpretation of results, and drafting of the manuscript. All authors read and approved the final manuscript.

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Declaration of interests

All authors have no potential competing interests to disclose.

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ANNEXES

Appendix 1. Search strategy for Medline

Appendix 2. Definition of terms

Appendix 3. Surgical categories

Appendix 4. CONSORT Checklist

Appendix 5. CONSORT-NPT Checklist

Appendix 6. TIDieR Checklist

Appendix 7. Categories of outcomes

Appendix 8. General characteristics of trials

Appendix 9. Results of intervention reporting

Appendix 1. Search strategy for MEDLINE

#1	"anesthesia"[MeSH] OR "anesthesia methods"[tiab] OR anesthetics[tiab] OR "anesthesia regional"[tiab]	182943
#2	"ambulatory surgical procedures"[MeSH] OR "ambulatory"[tiab] OR "ambulatory care"[MeSH] OR "ambulatory unit"[tiab] OR "outpatient"[tiab] OR "outpatient surgery"[tiab] OR "outpatient surgeries"[tiab] OR "day surgery"[tiab] OR "day surgery unit"[tiab] OR "day care surgery"[tiab] OR "day case surgery"[tiab]	208406
#3	(randomized controlled trial[Publication Type] OR controlled clinical trial[Publication Type] OR randomized[tiab] OR placebo[tiab] OR drug therapy[sh] OR randomly[tiab] OR trial[tiab] OR groups[tiab]) NOT (animals[mh] NOT humans[mh])	3755332
#4	"Anesthesiology" [jour] OR "Br J Anaesth" [jour] OR "Pain" [jour] OR "Anaesthesia" [jour] OR "Reg Anesth Pain Med" [jour] OR "Eur J Anaesthesiol" [jour] OR "Anesth Analg" [jour] OR "Int J Obstet Anesth" [jour] OR "Can J Anaesth" [jour] OR "J neurosurg Anesthesiol" [jour]	115104
#5	"N Engl J Med" [jour] OR "Lancet" [jour] OR "JAMA" [jour] OR "BMJ" [jour] OR "JAMA Intern Med" [jour] OR "Ann Intern Med" [jour] OR "Nat Rev Dis Primers" [jour] OR "J Cachexia Sarcopenia Muscle" [jour] OR " PLoS Med" [jour] OR "BMC Med" [jour]	401237
#6	#1 AND #2 AND #3 AND (#4 OR #5)	670

Appendix 2. Definition of terms

- *Ambulatory surgery:* An operation/procedure, or outpatient operation/procedure, where the patient is discharged on the same working day.
- *Outpatient:* A patient treated solely in the outpatient department, including such services as ambulatory procedure, interventional radiology, radiotherapy, oncology, renal dialysis, etc....
- *Anesthesia or Anesthesiology:* Perioperative medical act providing a state of sedation, analgesia and/or muscle relaxation compatible with the performance of a diagnostic or therapeutic invasive act. This includes general, regional, spinal, epidural, inhaling, intravenous and caudal anesthesia. In our study, this one is performed on an outpatient.

Appendix 3. Surgical categories

▪ Orthopaedic surgery
▪ Visceral surgery
▪ Vascular surgery
▪ Neurosurgery
▪ Urology
▪ Obstetrical gynecology
▪ Cardiac surgery
▪ Thoracic surgery
▪ Pediatric surgery
▪ Maxillo-facial surgery
▪ Dental surgery
▪ Endocrine gland surgery
▪ Ophthalmology
▪ Ear, nose and throat surgery
▪ Plastic surgery

Appendix 4. CONSORT checklist



CONSORT 2010 checklist of information to include when reporting a randomised trial*

Section/Topic	Item No	Checklist item	Reported on page No
Title and abstract			
	1a	Identification as a randomised trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	_____
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	_____
	2b	Specific objectives or hypotheses	_____
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	_____
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	_____
Participants	4a	Eligibility criteria for participants	_____
	4b	Settings and locations where the data were collected	_____
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	_____

Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	_____
	6b	Any changes to trial outcomes after the trial commenced, with reasons	_____
Sample size	7a	How sample size was determined	_____
	7b	When applicable, explanation of any interim analyses and stopping guidelines	_____
Randomisation:			
Sequence generation	8a	Method used to generate the random allocation sequence	_____
	8b	Type of randomisation; details of any restriction (such as blocking and block size)	_____
Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	_____
Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	_____
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	_____
	11b	If relevant, description of the similarity of interventions	_____
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	_____
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	_____

Results

Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analysed for the primary outcome	_____
	13b	For each group, losses and exclusions after randomisation, together with reasons	_____
Recruitment	14a	Dates defining the periods of recruitment and follow-up	_____
	14b	Why the trial ended or was stopped	_____
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	_____
Numbers analysed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	_____
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	_____
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	_____
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	_____
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	_____
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	_____
Generalisability	21	Generalisability (external validity, applicability) of the trial findings	_____
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	_____

Other information

Registration	23	Registration number and name of trial registry	_____
Protocol	24	Where the full trial protocol can be accessed, if available	_____
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	_____

*We strongly recommend reading this statement in conjunction with the CONSORT 2010 Explanation and Elaboration for important clarifications on all the items. If relevant, we also recommend reading CONSORT extensions for cluster randomised trials, non-inferiority and equivalence trials, non-pharmacological treatments, herbal interventions, and pragmatic trials. Additional extensions are forthcoming: for those and for up to date references relevant to this checklist, see www.consort-statement.org.

Appendix 5. CONSORT-NPT checklist

2017 CONSORT checklist of information to include when reporting a randomized trial assessing nonpharmacologic treatments (NPTs)*. Modifications of the extension appear in italics and blue.

Section/Topic Item	Checklist item no.	CONSORT item	Extension for NPT trials
Title and abstract			
	1a	Identification as a randomized trial in the title	
	1b	Structured summary of trial design, methods, results, and conclusions (for specific guidance see CONSORT for abstracts)	<i>Refer to CONSORT extension for abstracts for NPT trials</i>
Introduction			
Background and objectives	2a	Scientific background and explanation of rationale	
	2b	Specific objectives or hypotheses	
Methods			
Trial design	3a	Description of trial design (such as parallel, factorial) including allocation ratio	When applicable, how care providers were allocated to each trial group
	3b	Important changes to methods after trial commencement (such as eligibility criteria), with reasons	
Participants	4a	Eligibility criteria for participants	When applicable, eligibility criteria for centers and for <i>care providers</i>
	4b	Settings and locations where the data were collected	

Section/Topic Item	Checklist item no.	CONSORT item	Extension for NPT trials
Interventions	5	The interventions for each group with sufficient details to allow replication, including how and when they were actually administered	Precise details of both the experimental treatment and comparator
	5a		Description of the different components of the interventions and, when applicable, description of the procedure for tailoring the interventions to individual participants.
	5b		Details <i>of whether and</i> how the interventions were standardized.
	5c.		Details <i>of whether and</i> how adherence of care providers to the protocol was assessed or enhanced
	5d		<i>Details of whether and how adherence of participants to interventions was assessed or enhanced</i>
Outcomes	6a	Completely defined pre-specified primary and secondary outcome measures, including how and when they were assessed	
	6b	Any changes to trial outcomes after the trial commenced, with reasons	
Sample size	7a	How sample size was determined	When applicable, details of whether and how the clustering by care providers or centers was addressed
	7b	When applicable, explanation of any interim analyses and stopping guidelines	

Section/Topic Item	Checklist item no.	CONSORT item	Extension for NPT trials
Randomization:			
- Sequence generation	8a	Method used to generate the random allocation sequence	
	8b	Type of randomization; details of any restriction (such as blocking and block size)	
- Allocation concealment mechanism	9	Mechanism used to implement the random allocation sequence (such as sequentially numbered containers), describing any steps taken to conceal the sequence until interventions were assigned	
- Implementation	10	Who generated the random allocation sequence, who enrolled participants, and who assigned participants to interventions	
Blinding	11a	If done, who was blinded after assignment to interventions (for example, participants, care providers, those assessing outcomes) and how	Whether or not those administering co-interventions were blinded to group assignment If done, who was blinded after assignment to interventions (e.g., participants, care providers, <i>those administering co-interventions</i> , those assessing outcomes) and how
	11b	If relevant, description of the similarity of interventions	If blinded, method of blinding and description of the similarity of interventions
	11c		<i>If blinding was not possible, description of any attempts to limit bias</i>
Statistical methods	12a	Statistical methods used to compare groups for primary and secondary outcomes	When applicable, details of whether and how the clustering by care providers or centers was addressed

Section/Topic Item	Checklist item no.	CONSORT item	Extension for NPT trials
	12b	Methods for additional analyses, such as subgroup analyses and adjusted analyses	
Results			
Participant flow (a diagram is strongly recommended)	13a	For each group, the numbers of participants who were randomly assigned, received intended treatment, and were analyzed for the primary outcome	The number of care providers or centers performing the intervention in each group and the number of patients treated by each care provider or in each center
	13b	For each group, losses and exclusions after randomization, together with reasons	
	13c		<i>For each group, the delay between randomization and the initiation of the intervention</i>
	new		Details of the experimental treatment and comparator as they were implemented
Recruitment	14a	Dates defining the periods of recruitment and follow-up	
	14b	Why the trial ended or was stopped	
Baseline data	15	A table showing baseline demographic and clinical characteristics for each group	When applicable, a description of care providers (case volume, qualification, expertise, etc.) and centers (volume) in each group.
Numbers analyzed	16	For each group, number of participants (denominator) included in each analysis and whether the analysis was by original assigned groups	

Section/Topic Item	Checklist item no.	CONSORT item	Extension for NPT trials
Outcomes and estimation	17a	For each primary and secondary outcome, results for each group, and the estimated effect size and its precision (such as 95% confidence interval)	
	17b	For binary outcomes, presentation of both absolute and relative effect sizes is recommended	
Ancillary analyses	18	Results of any other analyses performed, including subgroup analyses and adjusted analyses, distinguishing pre-specified from exploratory	
Harms	19	All important harms or unintended effects in each group (for specific guidance see CONSORT for harms)	
Discussion			
Limitations	20	Trial limitations, addressing sources of potential bias, imprecision, and, if relevant, multiplicity of analyses	In addition, take into account the choice of the comparator, lack of or partial blinding, and unequal expertise of care providers or centers in each group
Generalizability	21	Generalizability (external validity, applicability) of the trial findings	Generalizability (external validity) of the trial findings according to the intervention, comparators, patients, and care providers and centers involved in the trial
Interpretation	22	Interpretation consistent with results, balancing benefits and harms, and considering other relevant evidence	
Other information			
Registration	23	Registration number and name of trial registry	

Section/Topic Item	Checklist item no.	CONSORT item	Extension for NPT trials
Protocol	24	Where the full trial protocol can be accessed, if available	
Funding	25	Sources of funding and other support (such as supply of drugs), role of funders	

**Additions or modifications to the 2010 CONSORT checklist. CONSORT = Consolidated Standards of Reporting Trials*

†The items 5, 5a, 5b, 5c, 5d are consistent with the Template for Intervention Description and Replication (TIDieR) checklist

Appendix 6. TIDieR checklist

The TIDieR (Template for Intervention Description and Replication) Checklist*:



Information to include when describing an intervention and the location of the information

Item number	Item	Where located **	
		Primary paper (page or appendix number)	Other (details) †
	BRIEF NAME		
1.	Provide the name or a phrase that describes the intervention.	_____	_____
	WHY		
2.	Describe any rationale, theory, or goal of the elements essential to the intervention.	_____	_____
	WHAT		
3.	Materials: Describe any physical or informational materials used in the intervention, including those provided to participants or used in intervention delivery or in training of intervention providers. Provide information on where the materials can be accessed (e.g. online appendix, URL).	_____	_____
4.	Procedures: Describe each of the procedures, activities, and/or processes used in the intervention, including any enabling or support activities.	_____	_____
	WHO PROVIDED		
5.	For each category of intervention provider (e.g. psychologist, nursing assistant), describe their expertise, background and any specific training given.	_____	_____
	HOW		

6.	Describe the modes of delivery (e.g. face-to-face or by some other mechanism, such as internet or telephone) of the intervention and whether it was provided individually or in a group. WHERE	_____	_____
7.	Describe the type(s) of location(s) where the intervention occurred, including any necessary infrastructure or relevant features. WHEN and HOW MUCH	_____	_____
8.	Describe the number of times the intervention was delivered and over what period of time including the number of sessions, their schedule, and their duration, intensity or dose. TAILORING	_____	_____
9.	If the intervention was planned to be personalised, titrated or adapted, then describe what, why, when, and how. MODIFICATIONS	_____	_____
10.‡	If the intervention was modified during the course of the study, describe the changes (what, why, when, and how). HOW WELL	_____	_____
11.	Planned: If intervention adherence or fidelity was assessed, describe how and by whom, and if any strategies were used to maintain or improve fidelity, describe them.	_____	_____
12.‡	Actual: If intervention adherence or fidelity was assessed, describe the extent to which the intervention was delivered as planned.	_____	_____

** **Authors** - use N/A if an item is not applicable for the intervention being described. **Reviewers** – use '?' if information about the element is not reported/not sufficiently reported.

† If the information is not provided in the primary paper, give details of where this information is available. This may include locations such as a published protocol or other published papers (provide citation details) or a website (provide the URL).

‡ If completing the TIDieR checklist for a protocol, these items are not relevant to the protocol and cannot be described until the study is complete.

* We strongly recommend using this checklist in conjunction with the TIDieR guide (see *BMJ* 2014;348:g1687) which contains an explanation and elaboration for each item.

* The focus of TIDieR is on reporting details of the intervention elements (and where relevant, comparison elements) of a study. Other elements and methodological features of studies are covered by other reporting statements and checklists and have not been duplicated as part of the TIDieR checklist. When a **randomised trial** is being reported, the TIDieR checklist should be used in conjunction with the CONSORT statement (see www.consort-statement.org) as an extension of **Item 5 of the CONSORT 2010 Statement**. When a **clinical trial protocol** is being reported, the TIDieR checklist should be used in conjunction with the SPIRIT statement as an extension of **Item 11 of the SPIRIT 2013 Statement** (see www.spirit-statement.org). For alternate study designs, TIDieR can be used in conjunction with the appropriate checklist for that study design (see www.equator-network.org).

Appendix 7. Categories of outcomes

	OUTCOMES
EFFICACY	Peroperative: Peroperative hypnosis, awakening, duration of the intervention, loco regional anesthesia Failure of the procedure Postoperative: pain Outpatient discharge: delayed discharge, hospitalization Quality of life: Return to work, return to driving Patient satisfaction Mortality
SAFETY	Cardiovascular complication Respiratory complication General complication: nausea, vomiting, dizziness, behavioural disorders

Appendix 8. General characteristics of trials

Trials	Country Location	Surgery Type	Number of arms	Sample Size	Intervention	Outcome	Population sex:	Population age:
							Male/Female	mean(sd)
Abdallah 2014	Canada	Gynecologic	arm 1	33	Paravertebral Block with Naropein	Quality of life	NR	53.1(12.3)
			arm2	31	Control		NR	56.5(12.5)
Abdallah 2015	Canada	Orthopaedic	arm 1	25	Control	Pain	10/15	46.1(14.3)
			arm2	25	DexIV: intravenous dexamethasone		15/10	46.1(15.9)
			arm3	25	DexP: perineural dexamethasone		13/12	51.8(15.3)
Abdallah 2016	Canada	Orthopaedic	arm 1	33	DEXp: perineural dexamethasone	Pain	26/7	42.0(37.8–46.2)**
			arm2	34	DEXiv: intravenous dexamethasone		25/9	36.1(31.7–40.5)**
			arm3	32	control		25/7	38.0(33.2–42.8)**
Abdallah 2016.2	Canada	Orthopaedic	arm 1	52	ACB: adductor canal block	Loco Regional Anesthesia (muscle strength recovery)	38/14	31.6(28.9–34.3)**
			arm2	48	FNB: femoral nerve block		26/22	33.3(30.7–35.9)**
Aguirre 2015	Switzerland	Orthopaedic	arm 1	65	Prilocaine(Intrathecal)	Loco Regional Anesthesia(installation time of the motor block)	40/25	48(18)
			arm2	64	Ropivacaine(Intrathecal)		41/23	51(24)
Ambrosoli 2016	Italie	Orthopaedic	arm 1	50	Prilocaine(Intrathecal)	Loco Regional Anesthesia(muscle strength recovery)	35/15	43.6(12.8)
			arm2	50	Mepivacaine(Intrathecal)		39/11	41.0(13.1)
Ambrosoli 2016.2	Italie	Orthopaedic	arm 1	41	Sciatic nerve catheter	Pain	5/36	57.2(13)
			arm2	41	Tibial nerve catheter		4/33	50.1(14)

* median(IQR), ** mean(range)

Appendix 8. General characteristics of trials

Trials	Country Location	Surgery Type	Number of arms	Sample Size	Intervention	Outcome	Population sex: Male/Female	Population age: mean(sd)
Aveline 2010	France	Visceral	arm1	134	Transversus abdominis plane	Pain	NR	58(31-84) *
			arm2	139	Ilioinguinal/iliohypogastric nerve		NR	60(41-83) *
Bachmann 2012	Finland	Visceral	arm1	40	Articaine in spinal anesthesia	Loco Regional Anesthesia (installation time of the sensitive block)	40/0	54(18-70) *
			arm2	40	Bupivacaine/fentanyl in spinal anesthesia		38/2	56(18-76) *
Bergmann 2012	Germany	Orthopaedic	arm1	76	SPI: surgical pleth index	Pain	66/10	48(18-69) *
			arm2	75	Control		72/3	44(18-74) *
Black 2010	Australia	Orthopaedic	arm1	22	Prilocaine (intrathecal)	Loco Regional Anesthesia (muscle strength recovery)	NR	50(23-77) *
			arm2	26	Bupivacaine (Intrathecal)		NR	50(23-80) *
Camponovo 2010	Switzerland	Orthopaedic	arm1	30	Hyperbaric Prilocaine 60 mg (Intrathecal)	Loco Regional Anesthesia (installation time of the motor block)	18/12	47(18)
			arm2	30	Hyperbaric Prilocaine 40 mg (Intrathecal)		15/15	50(13)
			arm3	30	Plain Prilocaine 60 mg (Intrathecal)		16/14	47(15)
Candido 2010	United States of America	Orthopaedic	arm1	34	Local anesthetic block + Placebo	Pain	17/17	42(21)
			arm2	35	Local anesthetic block + intramuscular buprenorphine		12/23	48(15)
			arm3	34	Local anesthetic block + buprenorphine block		16/18	46(21)
Chaparro 2010	Columbia	Plastic	arm1	80	Dexamethasone	Post operative Nausea/Vomiting	NR	29.5(7.3)
			arm2	80	Dexamethasone + Haloperidol		NR	30.1(7.5)

Appendix 8. General characteristics of trials

Trials	Country Location	Surgery Type	Number of arms	Sample Size	Intervention	Outcome	Population sex: Male/Female	Population age: mean(sd)
Dabu-Bondoc 2013	United States of America	Gynecologic	arm1	30	Dextrose	Post operative Nausea/Vomiting	NR	37.9(10.3)
			arm2	32	Control		NR	37.5(9.8)
DeOliveira 2011	United States of America	Gynecologic	arm1	47	TAP: Transversus abdominis plane block	Quality of life Loco Regional Anesthesia(muscle strength recovery)	N	36.5(8.5)
			arm2	23	Control		NR	38(10)
deSantiago 2009	Spain	Gynecologic	arm1	26	Lidocaine/fentanyl(Intrathecal)		NR	34(6)
			arm2	26	Levobupivacaine/fentanyl(Intrathecal)		NR	37(5)
Espelund 2013	Denmark	orthopaedic surgery	arm1	25	Ropivacaine	Pain	21/4	28(7)
			arm2	24	Control		17/7	33(11)
Fredrickson 2009	New zealand	Orthopaedic	arm1	32	Ropivacaine 0.2%	Pain	20/12	56(35-78) *
			arm2	33	Ropivacaine 0.4%		18/15	58(26-78) *
Gardiner 2012	Australia	Plastic	arm1	20	Paravertebral block with ropivacaine	Pain	0/20	34.1(10)
			arm2	20	Surgical infiltration of ropivacaine		0/20	34.9(8)
Gurnaney 2011	United States of America	Visceral	arm1	25	Rectus sheath block	Pain	14/11	7.7(5.1-17)**
			arm2	26	Local anaesthetic infiltration		14/12	7.9(5.1-16.4)**
Hanson 2013	United States of America	Orthopaedic	arm1	24	Adductor canal nerve block	Pain	20/4	54(11)
			arm2	24	Control		17/7	51(11)

Appendix 8. General characteristics of trials

Trials	Country Location	Surgery Type	Number of arms	Sample Size	Intervention	Outcome	Population sex: Male/Female	Population age: mean(sd)
Hendriks 2008	Netherland	Orthopaedic	arm1	36	Articaine	Loco Regional Anesthesia(duration of motor block)	21/15	47(22-60)**
			arm2	36	Prilocaine		26/10	46(22-69)**
Hong 2009	Korea	Urologic	arm1	37	LVHC: low volume/high concentration of Ropivacaine in caudal anesthesia	Dose of local anesthetic	NR	23.0(13.7)
			arm2	36	HVLC: high volume/low concentration of Ropivacaine in caudal anesthesia		NR	19.5(14.2)
Hong 2010	Republic of korea	Urologic	arm1	39	Caudal anesthesia + Placebo	Pain	NR	21.8 (months)(12-68)
			arm2	38	Caudal anesthesia + Dexamethasone		NR	20.0 (months)(13-57)
Ip 2013	Canada	Orthopaedic	arm1	13	Single shot in supraclavicular brachial plexus block	Pain	10/3	28.6(12.0)
			arm2	11	Catheter over needle in supraclavicular brachial plexus block		8/3	28.2(12.7)
Jacobsen 2011	Denmark	Orthopaedic	arm1	24	Lidocain(spinal)	Hospital discharge	17/7	40(12)
			arm2	21	Control		7/10	43(11)
Lacasse 2011	Canada	Orthopaedic	arm1	53	2-chloroprocaine(intrathecal)	Hospital discharge	24/29	53(16)
			arm2	53	bupivacaine(intrathecal)		20/30	54(16)
Lee 2012	Singapore	Visceral	arm1	37	Control	Hypnosis after general anesthesia(timing)	29/8	9.1(5-15) *
			arm2	38	Nitrous		30/8	9.5(6-15) *
Liu 2009	United States of America	Orthopaedic	arm1	115	Interscalene block with nerve stimulator	Post operative Nausea/Vomiting	NR	49(14)
			arm2	115	Interscalene block with ultrasound		NR	48(16)

Appendix 8. General characteristics of trials

Trials	Country Location	Surgery Type	Number of arms	Sample Size	Intervention	Outcome	Population sex: Male/Female	Population age: mean(sd)
Maalouf 2016	United States of America	Orthopaedic	arm1	77	Bupivacaine 40mL(interscalene block)	Hospital discharge	57/20	50(14.3)
			arm2	75	Bupivacaine 20mL(interscalene block)		56/19	51.1(14.5)
Majholm 2011	Denmark	Gynecologic	arm1	49	MAC: monitored anesthesia care	Hypnosis after general anesthesia(timing)	0/49	47(33-74) *
			arm2	42	TIVA: total i.v. anaesthesia		0/42	44.5(33-75) *
Mariano 2009	United States of America	Orthopaedic	arm1	15	Ropivacaine	Pain	11/4	55(28-65) *
			arm2	15	Placebo		9/6	42(20-58) *
Mariano 2009.2	United States of America	Plastic	arm1	20	Infraorbital block	Hospital discharge	11/9	40(14)
			arm2	20	Placebo		16/4	36(15)
O'Donnell 2009	Canada	Orthopaedic	arm1	17	Mepivacaine+fentanyl	Hospital discharge	9/8	50.5(15.9)
			arm2	17	Mepivacaine		8/9	42.7(14.7)
Peng 2010	Canada	Visceral	arm1	46	Placebo	Pain	13/33	47(21-65) *
			arm2	48	Pregabalin 50mg		14/34	46(22-65) *
			arm3	48	Pregabalin 75mg		20/28	43(22-65) *
Petersen 2013	Denmark	Visceral	arm1	29	TAP: Transversus abdominis block	Pain	28/1	49(13)
			arm2	30	Ilioinguinal nerve block		28/2	53(12)
			arm3	27	Placebo		26/1	54(13)

Appendix 8. General characteristics of trials

Trials	Country Location	Surgery Type	Number of arms	Sample Size	Intervention	Outcome	Population sex: Male/Female	Population age: mean(sd)
Petersen 2012	Denmark	Visceral	arm1	37	TAP: Transversus abdominis plane block	Pain	9/28	42(13.5)
			arm2	37	Placebo		12/25	43(17.0)
Petrar 2015	Canada	Orthopaedic	arm1	32	US-guided infraclavicular brachial plexus blockade	Hemidiaphragmatic paralysis	20/12	37(25-55) *
			arm2	32	US-guided supraclavicular brachial plexus blockade		21/11	40(28-52) *
Salviz 2013	United States of America	Orthopaedic	arm1	20	Continuous interscalene brachial plexus block	Pain	5/15	56(10)
			arm2	23	Single injection interscalene brachial plexus block		10/13	57(9)
			arm3	20	General anesthesia		7/13	52(12)
Seet 2010	Canada	Ambulatory(al l surgery)	arm1	50	Supreme laryngeal mask airway	Oropharyngeal leak pressure	31/19	48(16)
			arm2	49	ProSeal laryngeal mask airway		23/26	46(17)
Seet 2010.2	Canada	Ambulatory(al l surgery)	arm1	97	Manometers for Laryngeal Mask Airway	Pharyngeal adverse events: sore throat, dysphagia, dysphonia	52/45	47(16)
			arm2	103	Routine care		58/45	45(16)
Tan 2009	Ireland	Gynecologic	arm1	40	Propofol	Pain	NR	33.4(8.2)
			arm2	40	Sevoflurane		NR	34.9(7.9)
Teunkens 2016	Belgium	Orthopaedic	arm1	32	2-chloroprocaine(spinal anesthesia)	Loco Regional Anesthesia(muscle strength recovery)	21/11	47.5(21-76) *
			arm2	35	Lidocaine(spinal anesthesia)		16/19	49(20-66) *
			arm3	32	Bupivacaine(spinal anesthesia)		22/10	48(19-72) *

Appendix 8. General characteristics of trials

Trial	Country Location	Surgery Type	Number of arms	Sample Size	Intervention	Outcome	Population sex: Male/Female	Population age: mean(sd)
Theiler 2011	Switzerland	Ambulatory (all surgery)	arm1	106	Pediatric-sized i-gel	Oropharyngeal leak pressure	73/79	6.3(3.7)
			arm2	102	Ambu AuraOnce Laryngeal Mask		33/23	6.2(4)
Vieira 2010	United States of America	Orthopaedic	arm1	44	Interscalene brachial plexus blockade with Bupivacaine + Control	Loco Regional Anesthesia (installation time of the sensitive block)	33/11	48(12)
			arm2	44	Interscalene brachial plexus blockade with Bupivacaine + Dexamethasone		26/18	51(10)
Viscomi 2009	United States of America	Orthopaedic	arm1	20	Ketamine + Lidocaine-based intravenous regional anesthesia (IVRA)	Pain	7/13	54 (14)
			arm2	16	Ketamine systemic		10/6	46 (14)
Westergaard 2014	Denmark	Orthopaedic	arm1	29	Saphenous/ posterior branch of the obturator nerve block with Ropivacaine	Pain	12/17	31(24–47)
			arm2	30	Saphenous/ posterior branch of the obturator nerve block with Placebo		15/15	42(28–48)
White 2009	United States of America	Visceral	arm1	65	Sevoflurane	Recovery time	28/30	43(14)
			arm2	65	Desflurane		37/35	44(14)
Wiegel 2017	Germany	Orthopaedic	arm1	164	Interscalene brachial plexus block	Pain	98/66	53(13)
			arm2	165	Anterior suprascapular nerve block		106/59	55(13)
Zanaty 2015	Egypt	Dental	arm1	20	Nebulized Ketamine	Hypnosis after general anesthesia	11/9	3.3(0.72)
			arm2	20	Nebulized Dexmedetomidine + Ketamine		10/10	3.5(0.97)
			arm3	20	Nebulized Dexmedetomidine		9/11	3.3(0.92)
Zhang 2011	Canada	Orthopaedic	arm1	40	Laryngeal mask airway 80 cm H2O	Oropharyngeal leak pressure	23/17	49(16)
			arm2	40	Laryngeal mask airway 60 cm H2O		26/14	51(16)
			arm3	40	Laryngeal mask airway 40 cm H2O		22/18	51(14)

Appendix 9. Results of intervention reporting

Category	Item	Yes (%)	No (%)
Surgery	1	38 (73)	14 (27)
	2	6(12)	46 (88)
	3.1	5 (10)	47 (90)
	3.2	0 (0)	52 (100)
	3.3	0 (0)	52 (100.0)
	3.4	0 (0)	52 (100.0)
	4	1 (2.0)	51 (98.0)
	5	25 (48)	27 (52)
	6.1	28 (54)	24(46)
	6.2	11 (21)	41 (79)
	6.3	3 (6)	49 (94)
	7	0 (0)	52 (100)
	8	5 (10)	47 (90)
	Anesthesia	9	15 (29)
10.1		26 (50)	26 (50)
10.2		5 (10)	47 (90)
10.3		12 (23)	40 (77)
11		9(17)	43 (83)
12.1		52 (100)	0 (0)
12.2		52 (100)	0 (0)
12.3		52 (100)	0 (0)
12.4		51 (98)	1 (2)
12.5		32 (62)	22 (38)
12.6		44 (85)	8 (15)
12.7		35 (67)	17 (33)
13		12 (23)	40 (77)
14.1		41 (79)	11 (21)
14.2		23 (44)	29 (56)
14.3		42 (81)	10 (19)

	14.4	41 (79)	11 (21)
Organizational stream	15.1	23 (44)	29 (56)
	15.2	19 (37)	33 (63)
	15.3	20 (38)	32 (62)
	15.4	9 (17)	43 (83)
Standardization	16.1	49 (94)	3 (6)
	16.2	47 (90)	5 (10)
Modification/Tailoring	17.1	22 (42)	30 (58)
	17.2	19 (37)	33 (63)
	18.1	10 (19)	42 (81)
	18.2	8 (15)	44 (85)
Activity capacity of center	19.1	0 (0)	52 (100)
	19.2	0 (0)	52 (100)
Reproducibility	20	43 (83)	9(17)

CONCLUSION

Il est essentiel que les essais contrôlés randomisés fassent l'objet de rapports de haute qualité pour assurer la reproductibilité et la transparence. À l'aide d'un outil spécifiquement dédié à l'anesthésie ambulatoire, notre étude a permis d'établir la bonne qualité de la description de l'intervention anesthésique, mais souligne la nécessité d'améliorer la description des interventions chirurgicales et l'organisation du système de soins ambulatoires dans les études randomisées et contrôlées concernant l'anesthésie ambulatoire.

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RESUME

L'anesthésie ambulatoire est en plein essor dont la pratique repose sur un niveau de preuve qui n'a jamais été évalué. L'objectif de ce travail était d'évaluer la qualité des rapports d'intervention dans les essais cliniques comparatifs et randomisés dans le domaine de l'anesthésie ambulatoire.

Nous avons sélectionné des essais contrôlés randomisés évaluant les interventions anesthésiques en chirurgie ambulatoire, indexés dans Medline de 2008 à 2018 et publiés dans les 20 meilleures revues scientifiques en anesthésie et en médecine généraliste. Après avoir réalisé un mapping des publications, des types d'interventions et des outcomes, nous avons évalué la qualité du rapport d'intervention à l'aide d'une checklist adaptée au domaine de l'anesthésie ambulatoire, basée sur les recommandations CONSORT, CONSORT-NPT et TIDieR, en considérant trois dimensions essentielles de l'anesthésie ambulatoire (la procédure anesthésique, la procédure chirurgicale et les aspects organisationnels).

Nous avons inclus 52 essais. Dans l'ensemble, la qualité des rapports d'intervention utilisant les trois dimensions était correcte dans 41 % des études (moyenne : 21,3, sd :17,8). En ce qui concerne l'anesthésie, 45 études (87 %) ont correctement rapporté les éléments de notre liste checklist. La reproductibilité des interventions anesthésiques a été jugée très bonne par deux anesthésistes indépendants : 43 interventions (83 %) sur 52 avec une note moyenne de 7,2/10. Par contre, l'intervention chirurgicale n'a été décrite de façon satisfaisante que dans 25 études (48 %) et l'organisation du système ambulatoire uniquement dans 23 études (44 %).

La procédure purement anesthésique est correctement rapportée dans les essais contrôlés randomisés, mais en raison de sa complexité, l'évaluation de l'anesthésie ambulatoire nécessite plusieurs autres dimensions. Le système organisationnel et la procédure chirurgicale restent mal décrits. L'utilisation de notre checklist basée sur les 3 grandes dimensions pourrait constituer une approche exhaustive de l'évaluation des études sur l'anesthésie ambulatoire.

Mots-clés : anesthésie ambulatoire, essais contrôlés randomisés, intervention, rapport